SUMMARY OF THE
PROGRAM POLICY AND STRUCTURE COMMITTEE MEETING
MAY 23, 2001

The Program Policy and Structure Committee of the National Environmental Laboratory Accreditation Conference (NELAC) met on Wednesday, May 23, 2001, at 8:00 a.m and 1:00 p.m. Mountain Daylight Time (MDT) as part of the Seventh NELAC Annual Meeting in Salt Lake City, UT. The meeting was led by its chair, Dr. Kenneth Jackson of the New York State Department of Health. A list of action items is given in Attachment A. A list of participants is given in Attachment B. *The purpose of the meeting was to address items of importance as identified in the committee's previously distributed agenda.*

INTRODUCTION

Dr. Jackson began the meeting by welcoming the attendees. He then introduced the committee members, reviewed the ground rules, and added as an additional item to the agenda, the table referring to technologies, associated methods, and analytes.

AGENDA ITEMS

Proposed Scope of Accreditation

Mr. Art Burton presented a Field of Accreditation Tiered Approach which included four elements: Technology – Matrix – Method – Analyte/Analyte Group

The purpose of this approach would be to allow secondary accrediting authorities to simplify secondary accreditation. At the Sixth NELAC Interim Meeting (NELAC 6i) various options for changing the scope of accreditation were presented. A straw poll had been taken during that meeting and the consensus was to follow this option.

Technology:
Specific arrangement of analytical instruments and detection systems, such as gas chromatography/electron capture detector (GC/ECD) or inductively coupled plasma/mass spectroscopy (ICP/MS) was given as an example of different technology types.

Matrix:
The following example was presented to illustrate how different catagories are defined.
Description of sample type:

- Drinking Water - simple
- Non-Potable Water
  - Non drinking water.
- Solid and Chemical Materials
  - Soils, - hazardous waste analysis would fall into this category. Solvent solutions.
- Biological Tissues
  - For the future. Living tissues, mussels collected from a bay.
- Air and Emissions:

Ambient air and stack emissions.
Stack emissions to be deferred for 2 to 3 years

Method:
It was stressed that method include approved methods (EPA, SM, ASTM, USGS, etc), and performance-based measurement systems (PBMS). There was discussion regarding eliminating method as a tiered element but the general feeling was this should be kept in for the next few years.

Analyte/Analyte Group:
It was unclear at this time how analyte groups would be defined. However, all National Environmental Laboratory Accreditation Program (NELAP) accrediting authorities must use the same analyte groups to provide uniformity at the national level.

The primary advantage of the tiered approach is that other primary accrediting authorities can recognize a laboratory's primary accreditation for certain tiers without necessitating additional review and on-site assessment.

Examples of a tiered approach were given:

a. GC/ECD – Drinking Water – EPA 505 – Atrazine

b. Headspace GC/MS – Non-Potable Water – PBMS – Tetraethyl Lead

After the presentation there was considerable discussion as to whether there should be a three- or four-tier approach so a straw poll was taken of the audience. The overall preference was for a three-tier structure consisting of Matrix, Technology/Method, Analyte/Analyte Group. The decision was made to use the three-tier approach which combined technology with method. This did not seem to present a problem for the National Database committee although changes could take up to two years. It was also noted that the structure needs to be compatible with the proficiency testing (PT) requirements.

Field Activities

It was noted that if Chapter 7 is not approved on Friday in the voting session, the proposed language regarding field activities in Chapter 1 will have to be removed.

Frequently Asked Questions

Discussion continued on various points and one major consideration was whether examples should be included in the standard or put in a frequently asked question (FAQ) and referenced in the chapter. The decision was made to leave them in Chapter 1 as currently proposed.

Afternoon Session

The afternoon session was called to order at 1:10 pm. A conclusion to the discussion was held regarding Section 1.8.1. In addition to the changes that had been submitted prior to this meeting, changes to be voted on during the voting session are listed below:

Revised:

1.8.1 Scope of Accreditation

~~Laboratories must meet all relevant EPA program requirements, including quality assurance/quality control, use of specified methods, and other criteria.~~

~~The accreditation requirements shall be based on the tiered approach shown in Figure 1-3. Laboratories must meet the general requirements found in Chapter 5, and the specific quality control requirements for the type of testing being performed, as found in Appendix D of Chapter 5. Accreditation then will be granted for compliance with the relevant EPA program, the methods used by the laboratory, and for individual analytes determined by a particular method; e.g., a laboratory determining lead in drinking water, in compliance with the Safe Drinking water Act, by both inductively-coupled plasma mass spectrometry and graphite furnace atomic absorption spectrometry would be accredited for lead by both methods. Loss of accreditation for an analyte would not automatically result in loss of accreditation for all other analytes accredited under the method, provided the laboratory remained proficient in the determination of the other analytes.~~

Prior to NELAP initial accreditation and to maintain continuing accreditation, laboratories must meet all relevant EPA regulatory requirements, including quality assurance/quality control requirements. Laboratories must also meet the general requirements found in Chapter 5 and the specific quality control requirements for the type of testing being performed, as found in Appendix D of Chapter 5.

For laboratory testing, accreditation will be granted in conformance with a Field of Accreditation tiered approach as follows:

Matrix --- Technology/Method --- Analyte/Analyte Group

For Field Sampling, accreditation will be granted in conformance with a Field of Accreditation tiered approach as follows:

Matrix --- Field Sampling Method --- Analyte/Analyte Group.

Technology/method is a specific arrangement of analytical instruments, detection systems, and/or preparation techniques combined with a test method as defined in the glossary. Examples of technologies are GC/ECD, ICP/MS, etc. Technology groupings are listed in Appendix A. The tables in Appendix A will be amended from time to time as deemed appropriate by the Program Policy and Structure Committee.

Matrix is a description of sample type. Matrices include 1) Drinking Water, 2) Non-Potable Water (to include all aqueous samples that are not public drinking water, e.g. RCRA water samples, treatment plant additives, etc.), 3) Solid and Chemical Materials (to include soils, sediments, other solids and non-aqueous liquids), 4) Biological Tissues (not as yet defined in the scope of NELAC) and 5) Air and Emissions (to include ambient air and stack emissions). Other more specific matrices are used elsewhere in the standards.

Deleted Paragraph

Analyte/Analyte Group indicates that a lab may be accredited by individual analyte or for a group of analytes. If accredited by analyte group, the laboratory must perform a Demonstration of Capability (DOC) for each analyte, and the laboratory must perform all required QC and satisfactorily meet the PT requirements as defined in Chapter 2. It is possible that PT samples may not be available for all analytes. Accrediting authorities may grant accreditation by Analyte Group. All accrediting authorities accrediting by

analyte group must use the same Analyte Groups, which will be determined by the Program Policy and Structure Committee and published on the NELAC web site.

Typical examples of Fields of Accreditation using the tiered approach, including PBMS examples, are:

Drinking Water --- HPLC - UV/EPA 555 --- Pentachlorophenol

Non-Potable Water --- GC - MS/EPA 625 --- PAHs

Solid and Chemical Materials --- ICPAES/EPA 6010 --- Arsenic

Drinking Water --- GC - ECD/EPA 505 --- Atrazine

Drinking Water --- CVAA (with EPA 1631 extraction)/PBMS --- Mercury

Non-Potable Water --- Headspace GCMS/PBMS --- Tetraethyl Lead

No Change:

The following example shows the tiered approach applied to a laboratory seeking accreditation in hazardous waste organic testing under the auspices of RCRA. The laboratory must meet all the requirements listed in general laboratory (NELAC Chapter 5), chemistry (NELAC Chapter 5, Appendix D.1), the RCRA regulations (40CFR261), and the method(s) used (e.g., SW846 5030/~~8240~~ 8260). In all cases, a NELAC accredited laboratory must be accredited for the specific method it uses. In some cases the regulations mandate the method to be used (e.g., 40CFR261 specifies SW846 Method 1311, TCLP). In other cases the regulations provide guidance for the methods which can be used (e.g., 40CFR264, Appendix IX, suggests applicable methods). Finally, in some situations the regulations provide no guidance as to the methods to be used (e.g., 40CFR268 lists analytes required to be measured, with no guidance on methods). In those cases where the test method is not mandated by regulation, the laboratory must be accredited for the specific method used, as documented in the laboratory's SOP (see Chapter 5). This method must meet the relevant start-up, calibration, and on-going validation and QC requirements specified in Chapter 5. The tiered approach allows for the incorporation of performance based measurement systems (PBMS) by substituting PBMS for the specified analytical methods when allowed under EPA regulations.

~~The tiered approach eliminates redundancy by allowing for the incorporation of new methods or new instrumentation without the laboratories repeatedly demonstrating the basic requirements. This structure defines the scope of accreditation for inclusion on the laboratory accreditation certificate. The on-site assessment, proficiency testing evaluation, and data assessments are the processes for assessing the capabilities of the laboratories within the tiered structure. These processes, defined in Chapters 2 and 3, do not necessarily evaluate all tiers within the tiered structure; e.g., proficiency testing examines the determination of individual analytes in specific matrix types, and is not method-specific. However, they are comprehensive enough to assure the accrediting authority that a system is in place that produces data of known and documented quality.~~

Revised:

Additional accrediting authorities may recognize a laboratory's primary accreditation for certain tiers without additional review and on-site assessment.

For example, under a tiered approach:

1. A laboratory's home state (State A) only provides accreditation for Drinking Water. As primary accrediting authority, State A accredits the laboratory for the Field of Accreditation

   Drinking Water --- GC-ECD/EPA 505 --- Atrazine.

2. The laboratory then applies to a second state (State B) to be its primary accrediting authority for the Field of Accreditation

   Non-Potable Water --- GC-ECD/EPA 612 --- 1,2-dichlorobenzene.

3. State B recognizes the technology GC - ECD, since that technology was accredited by State A: i.e., State A has examined the instrumentation, checked run logs, interviewed the analyst(s) operating that instrument, etc.

4. To accredit the laboratory for the requested Field of Accreditation, State B may only require the SOP (for Method 612), the DOC, other QC data and satisfactory PT results (where PT's are available, see Chapter 2) for the analyte 1,2-dichlorobenzene. State B may obtain these documents from the laboratoryand PT providers as appropriate, review them and approve them without the need for an on-site assessment. If there is any concern about the laboratory performance, the NELAC standards allow any accrediting authority to conduct announced or unannounced on-site assessments at any time.

No change:
The procedures and conditions for interim accreditation are described in Chapter 4.

Glossary

The term "fields of testing" was changed to "fields of accreditation" as it gives a more accurate description. The Proficiency Testing Committee will use the term "fields of proficiency testing." Proposed changes to the Glossary are as follows:

Revised:
Field of ~~Testing~~ Accreditation: (previously Field of Testing) NELAC's approach to accrediting laboratories by ~~program~~ matrix, technology/method and analyte/analyte group. Laboratories requesting accreditation for a ~~program-method-analyte~~ matrix-technology/method-analyte/analyte group combination or for an up-dated/improved method are required to submit only that portion of the accreditation process not previously addressed (see NELAC, section 1.8 ff). (NELAC)

Revised:
Field of Proficiency Testing: NELAC's approach to offering proficiency testing by matrix, technology, and analyte/analyte group.

Revised:
Matrix: the ~~component or~~ substrate of a test sample.

~~Aqueous: any aqueous sample excluded from the definition of Drinking Water matrix or Saline/Estuarine source. Includes surface water, groundwater, effluents, and TCLP or other extracts.~~

Field of Accreditation Matrix: These matrix definitions shall be used when accrediting a laboratory (see Field of Accreditation):

Drinking Water: any aqueous sample that has been designated a potable or potential potable water source.

Non-Potable Water: any aqueous sample excluded from the definition of Drinking Water matrix. Includes surface water, groundwater, effluents, water treatment chemicals, and TCLP or other extracts.

~~Saline/Estuarine: any aqueous sample from an ocean or estuary, or other salt water source such as the Great Salt Lake.~~

~~Non-aqueous Liquid: any organic liquid with <15% settleable solids.~~

Solid and Chemical Materials: includes soils, sediments, sludges, products and by-products of an industrial process that results in a matrix not previously defined.

Biological Tissue: any sample of a biological origin such as fish tissue, shellfish, or plant material. Such samples shall be grouped according to origin.

~~Solids: includes soils, sediments, sludges and other matrices with >15% settleable solids.~~

~~Chemical Waste: a product or by-product of an industrial process that results in a matrix not previously defined.~~

Air and Emissions: whole gas or vapor samples including those contained in flexible or rigid wall containers and the extracted concentrated analytes of interest from a gas or vapor that are collected with a sorbent tube, impinger solution, filter, or other device. (NELAC)

Quality System Matrix: These matrix definitions are an expansion of the field of accreditation matrices and shall be used for purposes of batch and quality control requirements (see Appendix D of Chapter 5). These matrix distinctions shall be used:

Aqueous: any aqueous sample excluded from the definition of Drinking Water matrix or Saline/Estuarine source. Includes surface water, groundwater, effluents, and TCLP or other extracts.

Drinking Water: any aqueous sample that has been designated a potable or potential potable water source.

Saline/Estuarine: any aqueous sample from an ocean or estuary, or other salt water source such as the Great Salt Lake.

Non-aqueous Liquid: any organic liquid with <15% settleable solids.

Biological Tissue: any sample of a biological origin such as fish tissue, shellfish, or plant material. Such samples shall be grouped according to origin.

Solids: includes soils, sediments, sludges and other matrices with >15% settleable solids.

Chemical Waste: a product or by-product of an industrial process that results in a matrix not previously defined.

Air and Emissions: whole gas or vapor samples including those contained in flexible or rigid wall containers and the extracted concentrated analytes of interest from a gas or vapor that are collected with a sorbent tube, impinger solution, filter, or other device. (NELAC)

Revised:
Method: see Test Method

Revised:
Performance Based Measurement System (PBMS): a set of processes wherein the data quality needs, mandates or limitations of a program or project are specified and serve as criteria for selecting ~~appropriate test methods~~ measurement processes ~~to~~ which will meet those needs in a cost-effective manner. (NELAC)

Revised:
~~**PT Fields of Testing:** NELAC's approach to offering proficiency testing by regulatory or environmental program, matrix type, and analyte. (NELAC)~~

Revised:
~~**Reciprocity**~~ **Recognition:** Previously known as reciprocity. The mutual agreement of two or more parties (i.e., States) to accept each other's findings regarding the ability of environmental testing laboratories in meeting NELAC standards. (NELAC)[1.5.3]

No Change:
Technology: a specific arrangement of analytical instruments, detection systems, and/or preparation techniques.

No Change:
Test Method: an adoption of a scientific technique for a specific measurement problem, as documented in a laboratory SOP or published by a recognized authority. (NELAC)

Discussion continued regarding changing the word reciprocity to recognition. It was noted that the effect this wording change has on other chapters should be considered editorial changes. The remaining proposed changes to Chapter 1, that had been published prior to the meeting, were discussed. No further changes were proposed.

Tables of Technology and Methods

The proposed tables should be kept for information purposes only and should not be voted on. The accrediting authorities will need to update ~~it~~ the list of accreditations they offer, so the tables may be kept current. The question was raised as to whether the tables should be included in the bound standard or simply posted on the NELAC Website.

Comments on the format of the tables included minimizing the number of technologies to promote useability. There was also discussion about deeming methods equivalent; i.e., what criteria would be used? The chair requested written comments and suggestions to the committee. The committee resolved to refine the tables for presentation and discussion at NELAC 7i.

DATA INTEGRITY PROGRAM

A preliminary model of data integrity program was presented by Mr. Burton. This is a new concept based on previous discussions in the laboratory community. It consists of systems to deal with the data integrity question of how to install a laboratory system to prevent inappropriate data manipulation. The proposed model would reduce the opportunity to bend rules or other inappropriate data manipulation. An example of a current program is the American Council of Independent Laboratories' (ACIL) "seal of excellence" program. At the present time most of the chapters of the NELAC standard do not systematically address this issue. Several alternative methods were discussed.

Three Part Laboratory Systems Approach

A laboratory systems approach is a "proactive" approach and has three components. These include (1) alignment with core values, e.g., honesty – which is fundamental with data integrity, (2) senior management commitment/involvement – current management systems tend to reinforce improper behavior, and (3) counteract inappropriate/unethical data manipulation.

Four Part Laboratory Program

The four part laboratory program is in place, but frequently goes unnoticed. It includes (1) ethics training, (2) ethics contractual commitment (or agreement), (3) surveillance, and (4) documentation.

(1) Ethics Training – would be required and would include include annual refresher courses. All technical staff would be involved and the training would be conducted by senior management instructors. Core values would be emphasized and the concept of "heros" would be illustrated.

(2) Ethics Contractural Commitment (or agreement). This is a signed statement that the individual (technical employee) will conform to the ethical standards of the laboratory and also will not tolerate nonconformity in others. A laboratory ombudsman would be used to assure confidentiality and a receptive environment in which to discuss personal ethical dilemmas of observed unethical practices in others.

(3) Surveillance -- the method(s) used would be explained during training. One method that could be used consists of the random selection of data packages for in-depth review by a highly experienced and senior member of the staff. Electronic surveillance systems are available to scan GC and GC/MS data (Mintminer software).

(4) Documentation (for review during NELAC assessments)

(a) All data integrity incidents need to be documented and the documented stored in a central, but confidential laboratory location.

(b) All data integrity incidents must be thoroughly investigated. Findings such as disciplinary actions must be noted and client disclosures documented.

(c) For each NELAC audit, a written management summary of data integrity events that have occurred since the last audit must be available to the auditors for review. The summary should ensure that confidentiality is maintained with respect to laboratory staff names, but the summary must otherwise be a full disclosure document.

(d) When problems are encountered, must evaluate impact on reports and database.

Issues

Issues that were raised by the Data Integrity Program concept included whether or not small laboratories would support the concept. Comments and support for developing the language are needed.

Comments on Ethics Proposal

Ethics is the cornerstone of the Data Integrity Program and effective implementation is tough but it can be done. The Program Policy and Structure Committee will consider all the input at this meeting and will continue the discussion at NELAC 7i.

Proposed Changes & Timelines

After some discussion it was decided to recommend to the Conference that all changes to Section 1.8.1 and the Glossary would require two years before implementation, and all remaining changes to Chapter 1 would be effective July 1, 2001.

TASKS AHEAD

1. The Program Policy and Structure Committee is interested in receiving input over the next several months from the other NELAC committees regarding the plan to incorporate a Data Integrity Section in Chapter 1.

2. The committee intent is to include a Data Integrity section in Chapter 1 as soon as possible.

3. Continue to collect data for inclusion in the Tables of Technology and Methods.

Attachment A

ACTION ITEMS
PROGRAM POLICY AND STRUCTURE COMMITTEE MEETING
MAY 23, 2001

Item No.	Action	Date to be Completed
1.	Formulate/define Analyte Groups (in collaboration with PT Committee)	by NELAC 7i
2.	Complete/correct the Technology & Method Tables	by NELAC 7i
3.	Publish Technology and Method Tables on the Website	January 2002
4.	Publish in hard-copy (with the NELAC Standard)	July 2002

Attachment B

PARTICIPANTS
PROGRAM POLICY AND STRUCTURE COMMITTEE MEETING
MAY 23, 2001

Name	Affiliation	Address
Jackson, Kenneth Chair	New York State Dept. of Health	T: (518)485-5570 F: (518)485-5568 E: jackson@wadsworth.org
Aiello, Joseph	New Jersey Dept. of Environmental Protection-OQA	T: (609)633-3950 F: (609)777-1774 E: jaiello@dep.state.nj.us
Burton, Arthur	Sequoia Analytical Laboratory	T: (408)782-8167 F: (408)782-6308 E: aburton@sequoialabs.com
Clark, Stephen (absent)	USEPA/OW	T: (202)260-7159 F: (202)260-4383 E: clark.stephen@epa.gov
Eaton, Andrew	Montgomery-Watson Laboratories	T: (626)568-6425 F: (626)568-6324 E: andrew.eaton@mw.com
Giesler, Barbara	New Mexico Environment Dept (NMED)	T: (505)827-0152 F: (505)827-0160 E: barbara_giesler@nmenv.state.nm.us
Hogan, Mary Ann (absent)	Crystal Clear Ltd.	T: (302)655-8659 F: (302)655-8519 E: mahogan@home.com
McAninch, Thomas	Eastman Chemical Co. - Texas Operations	T: (903)237-5473 F: (903)237-6395 E: twmcan@eastman.com
Rosecrance, Ann (absent)	Core Laboratories	T: (713)328-2209 F: (713)328-2157 E: arosecrance@corelab.com
Sorbet, Elaine	Louisiana Dept. of Environmental Quality	T: (225)765-2406 F: (225)765-2408 E: elaines@deq.state.la.us
Askew, Suzanne (Contractor Support)	Research Triangle Institute	T: (919)541-7039 F: (919)541-7386 E: lsa@rti.org
Stella, Laurie (Contractor Support)	Research Triangle Institute	T: (919)541-6366 F: (919)541-7386 E: lbs@rti.org
Tatsch, Gene (Contractor Support)	Research Triangle Institute	T: (919)541-6930 F: (828)628-0659